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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/524,113    03/13/00    PATEL

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023492  
ABBOTT LABORATORIES  
DEPT. 377 - AP6D-2  
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ABBOTT PARK IL 60064-6050

HM12/0227

EXAMINER

BAHAE, M  
ART UNIT

PAPER NUMBER

1617  
DATE MAILED:

02/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/524,113

Applicant(s)

PATEL ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5 & 9.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

***Detailed Action***

Applicants' response to the restriction requirement and amendment submitted January 30, 2001 is acknowledged.

Applicant's election without traverse of the invention of Group I, claims 1-15, in Paper No. 8 submitted January 30, 2001 is acknowledged.

Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 8.

Claims 1-15 are examined on the merits herein.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "delivery system" recited in claims 13-15 is not a statutory category of invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The nature of the invention, e.g., composition, article of manufacture, etc., applicants' intended to be encompassed by claims 13-15 is unclear. It is suggested that the term "system" be replaced with a term which designates statutory subject matter.

In order to expedite prosecution, these claims will be examined on the merits as composition claims herein.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-9, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Krueger et al., (EP 0031603).

Krueger et al., (EP 0031603) teaches an emulsion composition delivery system comprising a lipid regulating agent (p-hexadecylaminobenzoic acid sodium salt), sesame oil and an emulsifier, which is a sorbitan fatty acid derivative, polysorbate 80, page 1, lines 17-22 and page 15, lines 25-34. Krueger et al., (EP 0031603) also teaches that the resulting suspension may be administered orally, page 15 lines 33-34.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 10-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger et al., (EP 0031603) in view of Suzuki et al., (EP 0700678) and The Merck Index. Note that both European Patents were submitted in the Information Disclosure Statement of September 1, 2000.

Krueger et al., (EP 0031603) teaches a composition for improved absorption of drugs which are poorly water soluble and poorly absorbed, abstract. More specifically, Krueger et al., (EP 0031603) teaches an emulsion composition or delivery system comprising a lipid regulating agent (p-hexadecylaminobenzoic acid sodium salt), sesame oil and an emulsifier, which is a sorbitan fatty acid derivative, polysorbate 80, page 1, lines 17-22 and page 15, lines 25-34. Krueger et al., (EP 0031603) also teaches that clofibrate is a hypocholesterolemic or "lipid regulating" agent, page 4, line 3. Moreover, Kreuger teaches the use of pharmaceutically acceptable oils broadly in his lipid-regulating emulsion composition, page 4 line 33-page 5, line 2. Finally, Kreuger teaches that the resulting suspension can be administered orally, in capsule form, page 5, lines 26-30.

Krueger et al., (EP 0031603) does not teach statins as lipid-regulating agents. Neither does it teach the employment of a co-solvent in the emulsion, nor does it teach the employment of atorvastatin particularly in the composition therein.

Suzuki et al., (EP 0700678) teaches the employment of antihyperlipidemic agents in general, and the employment of the particular lipid regulating agents pravastatin and derivatives thereof, in an oil and water emulsion composition, page 4, line 58. Suzuki et al. also teaches the

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employment of a hexane-ethanol mixed solvent in the lipid emulsion composition, page 17, line 31.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to use any of the statins known to be antihyperlipidemic agent, e.g. simvastatin, pravastatin and atorvastatin (see The Merck Index, page 146) in the Kreuger emulsion composition. It would have also been obvious to substitute any oil of vegetable origin for sesame oil in the emulsion composition of Kreuger. Furthermore, it would have been obvious to employ a co-solvent in the oil-in-water emulsion composition of Kreuger.

One of ordinary skill in the art would have been motivated to employ statins in the lipid regulating agent emulsion composition of Kreuger because statins are known lipid-regulating agents, and are thus expected to be useful similar to as clofibrate, p-hexadecylaminobenzoic acid sodium salt, or other lipid-regulating agents in Kreuger's composition. Similarly, one of ordinary skill in the art would have reasonably expected any pharmaceutically acceptable oil, including soya bean oil, to be similarly useful in the oil-in-water emulsion composition of Kreuger. See page 4, line 33-page 5 line 20 therein. Finally, the skilled artisan would have been motivated to use a co-solvent that does not effect the properties of the emulsion in order to improve the solubility as well as absorption of the lipid regulating agent in the host.

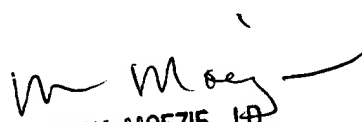
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
February 13, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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